

## Installation of Uninstalled Additional MRT Machines at Off-site Locations

### Issue Paper

#### I. Background

Recently we have had requests involving the off-site installation of MRT machines which are approved (or submitted for approval) as an expansion of an existing hospital MRT program.

In one case, two hospitals propose to form a multi-hospital joint-venture to operate a proposed additional linear accelerator of one of the hospital's programs at an off-site, outpatient location. In another case, a hospital wishes to use an additional MRT machine at an off-site location in conjunction with a medical group practice.

The existing standards for MRT require an existing program to demonstrate actual treatment visit volumes to support additional MRT machines. This is easier than the requirements for a new MRT program. In the case of a new program, new cancer cases must be documented for use of a stringent methodology. In many areas where an additional machine is possible (because treatment visit volumes can be shown), a new freestanding machine would be impossible (because sufficient new cancer cases cannot be documented).

To obtain an off-site machine in an area which does not have enough new cancer cases, a hospital with an existing program with enough volume for an additional machine, must apply for the additional machine and subsequently file a second CON for permission to relocate the new machine (or one of its older units) to another site within the same planning area. (Under the standards, relocation of an "existing" machine with the same planning area is approvable even if new cancer cases cannot be projected.) Operation of a relocated unit at a new geographic location in the same planning area is not considered a "new service.") After the relocation is complete, a third CON may be requested to change the ownership of the machine to a joint-venture or a third-party not connected with the hospital.

This three-step process can result in multi-hospital joint-ventures to improve MRT efficiency and quality. However, it can result in the establishment of a freestanding MRT unit owned by a non-hospital and based on the volume of a hospital program rather than documented new cancer cases as contemplated by the standards. This might be viewed as contrary to the intent of the standards.

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II. Issue

Is a MRT unit approved under Section 6 of the Standards as an expansion of an existing program, eligible to be relocated under Section 10 before it is actually installed at the site of the existing MRT service?

III. Discussion

Section 2(1)(b) states in part:

" . . . the relocation of a MRT unit meeting the requirements of Section 10 to a geographic location in the same planning area should not be considered as beginning operation of a MRT service/unit."

Section 10 applies only to the relocation of an "existing MRT service/unit."

Section 2(1)(p) defines "existing MRT service" to include:

" . . . the equipment at one geographic location used to provide MRT services including ...all MRT unit(s) which are listed on the department inventory of MRT units". [emphasis supplied]

Under the definition of "existing MRT service" in Section 2(1)(p), it appears that an MRT machine would be considered to be existing only when it is at one geographic location and used to provide MRT services. This implies that the unit must be installed before it is eligible to be relocated under Section 10.

The standards, however, do not include a definition of "existing MRT unit" and it is, therefore, arguable that a unit which is approved, but not yet installed, is eligible for relocation under Section 10 because it is listed on the Department Inventory. This argument could be made using Sections 2(1)(mm) and 2(1)(k).

Section 2(1)(mm) defines "relocation of an existing MRT service/unit" to mean a change in the geographic location within the same planning area of a MRT unit listed on the department inventory of MRT units. [emphasis supplied]

Section 2(1)(k) further defines "Department Inventory of MRT units" to include "...MRT units which are not yet operational but have a valid certificate of need issued under Part 222..."

IV. Recommendation

Because there appears to be some ambiguity in the Megavoltage Radiation Therapy Standard, we should look to the purpose of the standard for guidance. Any requirement for installation is intended to assure that units obtained as additional units for an existing MRT service are actually used as part of that service and considered, along with the other

units of the service, for purposes of future volume considerations and quality assurance.

In order to avoid protracted disputes over interpretation of the requirements of the Standard, and to promote the integration of services, ~~that~~ the relocation of a MRT unit which has been approved as an additional unit for a MRT program will be permitted before the unit is installed, if the applicant is willing to meet the requirements of Section 10 and in addition, to stipulate to all of the following:

- (a) The unit will continue to be considered as an additional unit of the service (i.e., the second, third, etc unit) for purposes of the volume requirements under Section 6 for a period of at least three years. (This stipulation will continue even if the unit is subsequently acquired by a third party unless waived by the Department.)
- (b) The unit will be operated for at least three years as part of a multi-site MRT program under the administration of the existing MRT service.
- (c) Subsequent acquisition of the off-site unit will be limited only to:
  - i) an applicant eligible to establish a new MRT service; or
  - (ii) an existing MRT service eligible to obtain approval for an additional MRT unit and willing to meet the same stipulations as the applicant.

If an applicant is unable or unwilling to meet these stipulations, on-site installation will be required.

ATTACHMENT A

Applicable Definitions and Standards

"Begin operation of a MRT service/unit" means the establishment of a non-special MRT service/unit at a geographic location where a MRT service/unit is not currently provided which will result in an increase in the number of non-special MRT units listed on the Department Inventory of MRT Units. The relocation of a MRT unit meeting the requirements of Section 10 to a geographic location within the same planning area shall not be considered as beginning operation of a MRT service/unit. [Sec. 2(1)(b)]

"Department Inventory of Megavoltage Radiation Therapy Units" means the list maintained by the Department of (i) the licensed MRT units operating pursuant to a valid certificate of need issued under Part 222 or former part 221, (ii) licensed, operating MRT units for which the operation of the unit did not require a certificate of need, and (iii) the MRT units which are not yet operational but have a valid certificate of need issued under Part 222 or former Part 221. The list will not include those units approved pursuant to Section 8 of these standards. The list will identify non-special and special purpose MRT units separately. [Sec. 2(1)(k)]

"Existing megavoltage radiation therapy service" means the facility and equipment at one geographic location used to provide MRT services including but not limited to the simulator(s), block fabrication materials, and all MRT unit(s) which are listed on the Department of Inventory of MRT Units. [Sec. 2(p)]

"Expand an existing MRT service" means increasing the number of MRT units (second, third, etc.) at the same geographic location of an existing MRT service. [Sec. 2(1)(q)]

"Geographic location" means either (i) the geographic location of a licensed health facility as defined in the certificate of need review standards applicable to the type of health facility or (ii) if the location is not a health facility as defined in Part 222 of the Code, a distinct geographic location separate from another location. [Sec. 2(1)(t)]

"Megavoltage radiation therapy program" means one or more MRT services operated at one or more geographic locations under the same administrative unit. [Sec. 2(1)(cc)]

"Relocation of an existing MRT service/unit" means a change in the geographic location within the same planning area of a MRT unit listed on the Department Inventory of MRT Units [Sec. 2(1)(mm)]

"An applicant proposing to expand an existing MRT service with an additional non-special MRT unit shall demonstrate that an average of 10,000 ETVs was performed in the most recent 12 month period on each of

the applicant's non-special MRT units listed on the Department Inventory of MRT Units at the location where the unit is to be added."

[Sec. 6(1)]

"An applicant proposing to acquire an existing MRT service/unit shall demonstrate that it meets all of the following:

- (a) the project is limited solely to the acquisition of an existing MRT service/unit.
- (b) The project will not change the number or type (special, non-special) of MRT units listed on the Department Inventory of MRT Units at the geographic location of the MRT service being acquired unless the applicant demonstrates that the project is in compliance with the requirements of Section 5 or 6, as applicable.
- (c) The project will not result in the replacement/upgrade of the MRT unit(s) to be acquired unless the applicant demonstrates that the requirements of Section 7 have also been met.
- (d) All MRT units at the service to be acquired are currently listed on the Department Inventory of MRT units.
- (e) The applicant agrees to operate the MRT service in accord with all applicable project delivery requirements set forth in Section 15 of these standards." [Sec. 9]

"An applicant proposing to relocate an existing MRT service/unit shall demonstrate that it meets all of the following:

- (a) The MRT unit(s) to be relocated is listed on the Department Inventory of MRT Units.
- (b) The relocation of the MRT unit will not change the number or type (special, non-special) of MRT units in the planning area.
- (c) The new geographic location will be in the same planning area as the existing geographic location.
- (d) The project will not result in the replacement/upgrade of the MRT unit(s) to be relocated unless the applicant demonstrates that the requirements of Section 7, as applicable, have also been met.
- (e) The unit to be relocated is not a special purpose unit unless the location to which the special purpose unit is to be relocated meets the requirements of Section 6, as applicable.
- (f) The applicant agrees to all applicable project delivery requirements set forth in Section 15 of these standards." [Sec. 10]